TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA center	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
CDRH	2,465	1	2,465	137	337,705
CBER	79	1	79	137	10,823
Total					348,528

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents are medical device manufacturers subject to FDA's laws and regulations. FDA's annual estimate of 2,544 submissions is based on experienced trends over the past several years. FDA's administrative and technical staffs, who are familiar with the requirements for current Pre-Submissions, estimate that an average of 137 hours is required to prepare a Pre-Submission.

Dated: October 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–25359 Filed 10–19–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Comments on the Proposed Measures and 2020 Targets for the National Action Plan for Adverse Drug Event Prevention: Inpatient and Outpatient Measures for Reduction of Adverse Drug Events From Anticoagulants, Diabetes Agents, and Opioid Analgesics

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Office of Disease Prevention and Health Promotion (ODPHP), on behalf of the U.S. Department of Health and Human Services (HHS) Federal Interagency Steering Committee for Adverse Drug Events, proposes new measures and targets for adverse drug events (ADEs) from anticoagulants, diabetes agents, and opioid analgesics for the *National Action Plan for Adverse Drug Event Prevention* (*ADE Action Plan*). Based on input from the Federal Interagency Workgroups for Adverse Drug Events, six national measures and targets for the reduction of ADEs are being proposed. Each drug class highlighted in the *ADE Action Plan* (anticoagulants, diabetes agents, and opioid analgesics) includes a proposed inpatient and outpatient measure to track national progress in reduction of ADEs from these drug classes. The proposed targets will reflect improvement efforts over a four to six year period since the release of the *ADE Action Plan* in August 2014. As such, HHS is proposing a baseline year of 2014 for five of the measures and 2016 for one measure. All targets are to be achieved by 2020. HHS invites interested public and private professionals, organizations, and consumer representatives to submit written comments on the proposed 2020 ADE targets, found at *https://health.gov/hcq/ade-measures.asp.*

DATES: Comments on the proposed ADE 2020 measures and targets must be received no later than 5 p.m. on November 21, 2016.

ADDRESSES: Interested persons or organizations are invited to submit written comments by any of the following methods:

- *Email: OHQ@hhs.gov* (please indicate in the subject line: Proposed ADE Measures and Targets)
- *Mail/Courier:* Office of Disease Prevention and Health Promotion, Attn: Division of Health Care Quality, Department of Health and Human Services, 1101 Wootton Parkway, Suite LL100, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Anna Gribble, Health Policy Fellow, Office of Disease Prevention and Health Promotion, via email at *anna.gribble@hhs.gov.*

SUPPLEMENTARY INFORMATION: In September 2012, in response to heightened awareness of the contribution of ADEs to the burden of health care-related harm and costs, the Office of the Assistant Secretary for Health (OASH) marshaled the wide-ranging and diverse resources of federal partners to form an extensive interagency partnership, the Federal Interagency Steering Committee and Workgroups for Adverse Drug Events, whose goals would be to develop the *ADE Action Plan,* as well as identify measures to track national progress in reducing ADEs and targets to meet based on those measures.

ODPHP, in conjunction with the Federal Interagency Steering Committee and three Federal Interagency Workgroups, developed and released the final *ADE Action Plan* in 2014. The *ADE Action Plan* seeks to engage all stakeholders in a coordinated, aligned, and multi-sector effort to reduce ADEs that are clinically significant, account for the greatest number of measurable harms as identified by existing surveillance systems, and are largely preventable; these were identified as ADEs resulting from inpatient and outpatient use of anticoagulants, diabetes agents, and opioid analgesics (with specific focus on ADEs from therapeutic use of opioids). The *ADE Action Plan* identifies the federal government's highest priority strategies and opportunities for advancement, which will have the greatest impact on reducing ADEs. Implementation of these strategies is expected to result in safer and higher quality health care services, reduced health care costs, informed and engaged consumers and ultimately, improved health outcomes. The reduction of ADEs subsequent to implementation of these strategies will be tracked by the proposed measures and will aim to meet the targeted reduction rate by 2020.

The six proposed measures use data from the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA). The inpatient and outpatient measures for anticoagulants and diabetes agents and the outpatient measure for opioids will set baseline rates using data from 2014 and establish targets to be achieved by 2020. The inpatient opioids measure will have a 2016 baseline and a 2020 target year. The inpatient opioids measure will use data from AHRQ's Quality Safety Review System (QSRS) which will begin collecting data in 2016. The inpatient measures for anticoagulants and diabetes agents will use AHRQ's Medicare Patient Monitoring System (MPSMS) for 2015

and QSRS for 2016–2020 and data will be adjusted accordingly. MPSMS did not include an opioids specific measure and QSRS now allows AHRQ to now track inpatient opioids adverse drug events.

Descriptions of the surveillance systems, measures, and targets can be found here: *https://health.gov/hcq/ade-measures.asp.*

Interested persons or organizations are invited to submit written comments in response to the proposed measures and targets. Written comments should not exceed more than two pages per ADE measure. The comments should reference the specific measure or target to which feedback refers. To be considered, the person or representative from an organization must self-identify and submit the written comments by close of business on November 21, 2016.

Dated: September 30, 2016.

Don Wright,

Deputy Assistant Secretary for Health, Director, Office of Disease Prevention and Health Promotion Office of the Assistant Secretary for Health.

[FR Doc. 2016–25424 Filed 10–19–16; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Genetics and Genomics.

Date: October 25, 2016.

Time: 3:30 p.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Richard A. Currie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1108, MSC 7890, Bethesda, MD 20892, (301) 435–1219, *currieri@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Risk, Prevention, and Health Behavior.

Date: October 31–November 1, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Martha M. Faraday, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, MSC 7808, Bethesda, MD 20892, (301) 435–3575, *faradaym@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Brain injury.

Date: November 7, 2016.

Time: 11:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Samuel C. Edwards, Ph.D., IRG CHIEF, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 14, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–25336 Filed 10–19–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel Rapid Assessment of Zika Virus (ZIKV) Complications (R21).

Date: November 14, 2016

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: Travis J. Taylor, Ph.D., Scientific Review Officer Scientific, Review Program, Division of Extramural Activities, Room 3G62B, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5082, *Travis.Taylor@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 14, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–25339 Filed 10–19–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Invention; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology